DATA REGISTRIES AND DATA COLLECTION AND USE ISSUES

DA1

USING MEDICATION HISTORY TO MEASURE INDICATION BIAS

Leader S, Mallick R
Pracon, Reston, VA, USA

Although observational studies are a relatively inexpensive and rapid alternative to randomized controlled trials, critics argue that observational studies lack internal validity. For example, indication bias may limit the reliability of outcomes data from observational studies on the cost or safety of alternative pharmacotherapy. The workshop will focus on the novel use of data on prior medications to document the extent of confounding by indication. Current research on use of anti-hypertensive and anti-anginal medications in a Medicaid population will be used to illustrate recommended methods for designing and conducting observational studies. Topics covered will include assessing and classifying the duration and classes of prior medication history, sequencing of risk factors and adjusting for severity of disease. The on-going controversy over the safety of calcium channel blockers will be examined in light of evidence on confounding by indication. The presenters' own research will be used to explore the evidentiary basis for current claims and counter claims as well as the weakness of data on the key intervening variable-exposure to the study drugs. The workshop material is aimed at researchers with hands-on experience using administrative databases as well as industry sponsors of outcome studies. The workshop addresses the themes of enhancing the usefulness of outcomes research for providers and insurers by strengthening current methods for identifying and eliminating systematic biases.

DA2

THE ROLE OF PATIENT REGISTRIES IN DISEASE MANAGEMENT AND OUTCOMES RESEARCH

Hartz SC, Huse DM
Medical Research International, Burlington, MA, USA

There is growing enthusiasm for the use of health-care claims databases representing thousands or even millions of covered lives to assess the potential value of medical interventions, including pharmaceuticals and disease management programs. However, evaluations of the effectiveness and safety of such interventions conducted in this manner may be confounded by clinical or patient differences between treatment groups that are not captured in readily-available databases. Patient registries designed to meet specific research objectives can provide a more robust source of data for outcomes research and disease management by linking administrative databases, medical records, patient questionnaires, death certificates, etc. The result is comprehensive longitudinal information on diagnosis, treatment, course of illness, outcomes, quality of life, and costs of the diseases of interest. By seeking the informed consent of participants the registry can also obviate growing public concerns about the research use of confidential health-care data. Workshop participants will receive a detailed overview of the registry concept and implementation, emphasizing its research value as well as its potential role in support of new product development and marketing and in the development and testing of disease management programs. Case studies of successful registries in the fields of reproductive health, cardiovascular disease, and asthma will be used to illustrate general principles and methods. Persons who have responsibility for planning or conducting outcomes research or disease management programs in the pharmaceutical industry, hospitals, or managed care will benefit from attending this workshop.

DA3

USING COMMUNITY PHARMACIES TO CONDUCT OUTCOMES RESEARCH

Ungar WJ
Innovus Research Inc., Burlington, Ontario, Canada

Studies of effectiveness require that health outcomes be measured in heterogeneous samples of patients. The Pharmacy Medication Monitoring Program (PMMP) is an outcomes research program which uses community pharmacies to recruit study subjects, resulting in a broad sample of patients treated by physicians with diverse practice patterns. Patients are followed prospectively and undergo repeat telephone interviews at specified intervals. The purpose of this workshop is to demonstrate how community pharmacies can be used to perform high

quality, prospective outcomes research. The methods for establishing a network of pharmacies, recruiting patients, and obtaining patient informed consent will be described. The procedures for developing telephone questionnaires and for collecting data on a broad range of topics, such as patient demographics, drug utilization and compliance, prescribing patterns, health services utilization, adverse events, quality of life, out-of-pocket expenditures and productivity losses will be discussed. Finally, the applications of community pharmacy-based outcomes research studies will be presented. These include pharmacoeconomic evaluations for formulary registration, drug utilization review for improving therapeutic regimens, developing disease management strategies for optimizing care, patient profiling for investigating utilization and compliance patterns and measuring health outcomes to assess the impact of health policy decisions. This workshop will benefit industrial and academic researchers engaged in prospective pharmacoeconomic assessments, health services evaluations and outcomes research. Individuals interested in outcomes research methodology and the relationship between outcomes research and health policy decision-making may also benefit from attending.

DA4

CONSTRUCTION OF A VALIDATED, NORMALIZED, GRANULAR ADMINISTRATIVE DATABASE AND ITS USE IN CLINICAL OUTCOMES IMPROVEMENT, CLINICAL RESEARCH, AND PHARMACOECONOMIC RESEARCH

Morris S[1], Seltzer J[2], Bryant D[1]
[1]Premier, Inc., Charlotte, NC, USA; [2]Premier Research Worldwide, Philadelphia, PA, USA

The growth in the number of studies analyzing healthcare costs has been exponential. However, recently published data cast doubt about their applicability. We hypothesize that this situation may be, in part, due to the lack of timely, validated, standardized databases. Additionally, many of the rigorous procedures developed to assure veracity of clinical research data have not been consistently applied to the conduct of outcomes research. Similarly, doubts about the accuracy and timeliness of administrative information may hinder its application to the processes of clinical research. We suggest that through careful construction of a clinical financial database and judicious application of clinical research tools and practices, some of these barriers may be overcome.

This workshop aims to:

1) Describe the Perspective Comparative Database (PCD), Premier, Inc.'s standardized nationwide 150-center clinical financial dataset through:
   - review of the methodology by which standard data elements are defined, normalized, mapped and validated;
   - review of the methodology by which standardized costs are validated.
2) Describe PCD's efficacy in the research arena:
   - provide examples of clinical outcomes improvement;
   - provide examples of application to clinical research in the arena of patient identification and protocol development;
   - provide examples of combination with clinical research tools in performance of pharmacoeconomic studies.
3) Suggest methods by which a combined PCD/clinical information database might allow for rapid acquisition and analysis of pharmacoeconomic data.

This workshop is intended for industry professionals and non-industry researchers involved in applied pharmacoeconomics, decision support systems, and clinical research.

DA5

DISEASE STATE MANAGEMENT TRACKER: IMPLEMENTING, TRACKING, AND EVALUATING CLINICAL PATHWAYS AND OUTCOMES

Ambegaonkar AJ, Day D, Main J, Lubowski T, Yamaga C, Van Vleet J
Clinical Pharmacy Outcomes Research, Pfizer Inc., New York, NY, USA

Although clinical guidelines have been gaining widespread acceptance as a management tool, practical difficulties in implementation and measurement of outcomes have been obstacles in their widespread use. Their complexity may discourage consistent use in everyday practice, while the lack of data tracking their implementation has limited the assessment of outcomes. Disease State Management Tracker (DSMT) addresses these concerns with a system that makes it easy for the practitioner to enter patient assessments and track services received, as well as monitor patient progress and outcomes. DSMT is based on the components of disease state management, namely: treatment algorithms, clinical decision making, and outcomes reporting.

Complex treatment algorithms are easily stored and analyzed using either retrospective or prospective data. The DSMT software was developed as an application for the Windows 95/NT environment. The workshop will be presented in the form of an overview of the DSMT and its functionalities while using community acquired pneumonia as an example disease state. The attendee will be able to convert locally or nationally developed clinical pathways and enter them into the DSMT. Next, patient assessment, assignment into management cells for provision of services, and determination of patient outcomes in the DSMT will be reviewed. Finally the capability of DSMT to generate extensive reports will be demonstrated. Some standard reports include determination of cost of treatment via the clinical pathway as well as cost of deviations from the pathway. DSMT is being used for various disease states including community acquired pneumonia, asthma, osteo-arthritis, osteoporosis as well as in several